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LIFESCIENCES INC

Miconazole FUNGARIN

20 mg/g (2% w/w) Oral Gel
Antifungal

Formulation of the product

Each gram contains:

Miconazole, BP	20 mg
Ethanol (96%), BP.....	7.59 mg
In an aqueous gel base	q.s.

Description of the product

White homogenous translucent oral gel

What is in the Medicine?

Fungarin gel contains 20 mg of miconazole.

Strength of the Medicine

See the formulation.

What is this Medicine used for?

Fungarin (Miconazole) oral gel is a medicine which is used to treat fungal infections of the mouth, throat and gullet. It contains miconazole which works by destroying the fungus that is present.

How much and how often should you use this Medicine?

Infections of the mouth and throat

Adults and Children over 2 years old: 2.5 ml (half a 5 ml spoonful) of gel applied four times a day after meal.

Infants 4 months - 2 years old: 1.25 ml (one quarter of a 5 ml spoonful) of gel applied four times a day after meals. Each application should be divided into smaller portions.

Infants 4 months - 6 months old, and is premature or has slow development: check with your doctor before using this medicine.

The gel should not be swallowed immediately, but kept in the mouth as long as possible.

The treatment should be continued for at least a week after the symptoms have disappeared.

For oral candidiasis, dental prostheses should be removed at night and brushed with the gel.

When should you not take this Medicine?

- Known hypersensitivity to miconazole, other imidazole derivatives or to any of the excipients (purified water, pregelatinized potato starch, alcohol, polysorbate 20, sodium saccharin, cocoa flavor, orange flavor and glycerol).
- In infants less than 4 months of age or in those whose swallowing reflex is not yet sufficiently developed.
- In patients with liver dysfunction.
- Co-administration of the following drugs that are subject to metabolism by CYP3A4.
- Substrates known to prolong the QT-interval e.g., astemizole, cisapride, dofetilide, mizolastine, pimozone, quinidine, sertindole and terfenadine.
- Ergot alkaloids
- HMG-CoA reductase inhibitors such as simvastatin and lovastatin.
- Triazolam and oral midazolam

Care that should be taken when taking this Medicine?

- Miconazole is systemically absorbed and is known to inhibit CYP2C9 and CYP3A4 which can lead to prolonged effects of warfarin. Bleeding events, some with fatal outcomes, have been reported with concurrent use of miconazole oral gel and warfarin. If the concomitant use of Fungarin Oral Gel with an oral anticoagulant such as warfarin is planned, caution should be exercised and the anticoagulant effect must be carefully monitored and titrated.
- Patients should be advised that if they experience unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in the urine, black tarry stools or coffee ground vomit, to stop treatment with miconazole and seek medical advice.

• Severe hypersensitivity reactions, including anaphylaxis and angioedema. If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued.

• In patients using certain oral hypoglycaemics such as sulphonylureas, an enhanced therapeutic effect leading to hypoglycaemia may occur during concomitant treatment with miconazole and appropriate measures should be considered.

Choking infants and young children:
Particularly in infants and young children (aged 4 months – 2 years), caution is required, to ensure that the gel does not obstruct the throat. Hence, the gel should not be applied to the back of the throat. Each dose should be divided into smaller portions and applied into the mouth with a clean finger. Observe the patient for possible choking.
Also due to the risk of choking, the gel must not be applied to the nipple of a breast-feeding woman for administration to an infant.

Undesirable effects of this medicine stop using Fungarin oral gel and consult your doctor if you notice the following:

- Sudden swelling of the face, lips, tongue and throat; difficulty swallowing; hives (also known as nettle rash or urticaria) and breathing difficulties (angioedema, anaphylactic reactions); severe irritation, reddening or blistering of your skin.
- Severe skin disorders with peeling and/or rashes with small pus-containing pimples (with a fever) or blistering of your skin, mouth, eyes and genitals.
- Light headedness, generalized itch, wheezing or difficulty breathing.
- If you are taking medicines to thin the blood (anticoagulants), such as warfarin; unexpected bleeding or bruising, nosebleeds, coughing up blood in the urine black tarry stools or coffee ground vomit.

What should you do if you miss a dose?

- Do not apply the missed does of gel
- Apply the next dose of gel as usual and keep using it as your doctor has told you
- Do not use a double dose of gel to make up for a missed dose

Signs of symptoms of Overdose
In the events of accidental overdose, vomiting and diarrhea may occur.

What to do when you have taken more than the recommended dosage?
If you use more Fungarin oral gel than you were told or if someone has taken any, talk to a doctor or go to the nearest hospital casualty department straight away.

How should you keep this medicine?
Keep out of reach and sight of children.
Store the gel in its original packaging.
Do not store above 30°C.

When should you consult your doctor?
Please refer to undesirable effects of this medicine.

Import and Distributed by:
biocare
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Manufactured by:
S Kant HEALTHCARE Ltd.
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Vapi, Gujarat, 396 195, India

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph and to email address: pv@biocarelifesciences.com

Seek medical attention immediately at the first sign of any adverse drug reaction.

SHELF-LIFE: 36 months

Reg. No.: DRP-12629

Date of First Authorization: September 16, 2022

Date of Revision of Patient Information Leaflet: August 2023

Product Name : FUNGARIN_Miconazole_15g_Al_u_PI		Item : Insert		Date : 22/01/24
Co-ordinator : Kishori		Artist : NITIN		
Language : English				
Actual Size : 150 x 150 mm (L x H)				
Colours : Black 				
Reference Artwork item code:		EPP No.: 489A		CCF No.:
Leaflet : J. K. Maplitho 60 GSM Folding Size 				
If any Special instruction Instructions: Any deviation must be brought to the notice of packaging development co-ordinator immediately.				
Checked by	R.A.	B.H.	F n D	PDC
A/w Initiation date:				
A/w Final date:				